(b) screening the resulting transfected somatic cells *in vitro* to select a cell, wherein the selected cell is stably transfected with the DNA sequence [by integration of the DNA sequence into the chromosome of the selected cell or in a replication competent plasmid to impart to] so that the selected cell has the permanent capacity to direct expression of the DNA sequence;

(c) cloning and expanding the selected somatic cell *in vitro;* and

(d) injecting the resulting transfected, screened, cloned, and expanded somatic cells into the recipient subject;

wherein the DNA sequence comprises the gene and a promoter capable of functioning in the somatic cells; and

wherein, following injection of the [clonal] transfected, screened, cloned, and expanded somatic cells into the recipient subject, the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

104. (Amended) A method of [for] transferring a gene into a recipient subject, comprising:

(a) providing somatic cells;

(b) transfecting [said] the somatic cells *in vitro* with a DNA sequence comprising [said] the gene and a promoter capable of functioning in [said] the somatic cells, wherein [said] the gene encodes a gene product, and wherein [said] the somatic cells are stably transfected with [said] the gene [by integration of the gene into the

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

chromosomes of the somatic cells or in replication competent extrachromosomal plasmids to impart to said] so that the somatic cells have the permanent capacity to direct expression of [said] the gene upon induction of [said] the promoter;

(c) screening the resulting transfected somatic cells *in vitro* to select a transfected somatic cell, wherein [said] the screening comprises characterizing [said] the transfected somatic cell with respect to expression and regulation of the gene by assaying for translation of the mRNA into the gene product;

(d) cloning and expanding, *in vitro,* the transfected and screened somatic cell selected in step (c) to form [said] 10^5 - 10^{10} transfected, screened, cloned and expanded somatic cells, and

(e) combining the 10^5 - 10^{10} transfected, screened, cloned, and expanded somatic cells with a physiologically acceptable buffer or carrier; and

H2

(f) injecting the resulting transfected, screened, cloned, and expanded cell preparation into the recipient subject,

wherein, following injection of the [clonal] transfected, screened, cloned, and expanded somatic cells into the recipient subject, the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

105. (Amended) The method of transferring a gene into a recipient subject of any one of claims [72] 73 or 104, wherein the transfected gene encodes human growth hormone.

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

106. (Amended) The [transfected cell preparation] method of transferring a gene into a recipient subject of any one of claims [72] 73 or 104, wherein the transfected gene encodes insulin.

Please add the following new claims 107-108:

--107. The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the DNA sequence integrates into the chromosome of the selected cell.

108. The method of transferring a gene into a recipient subject of any one of claims 73 or 104, wherein the DNA sequence replicates as an extrachromosomal plasmid.--

REMARKS

Applicant has canceled claim 79 without prejudice or disclaimer. Independent claim 72 reads upon the subject matter of this dependent claim.

Applicant has amended claims 72 and 104 to further define the transfected, screened, cloned, and expanded somatic cells used in the method of these claims. Applicant has also amended claims 72 and 104 to delete language specifying how the gene is stably integrated into the transfected cell and added new claims 107-108 to

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000